MINUTES OF THE IDAHO STATE BOARD OF PHARMACY JANUARY 6, 2011

HILTON GARDEN INN SPECTRUM – BOISE, IDAHO

This meeting of the Board is held to conduct regular Board business.

Chairman Holly Henggeler, Pharm D, called the meeting to order on January 6, 2011 at 8:02 a.m. In attendance were Board members Berk Fraser, R.Ph.; Nicole Chopski, Pharm D; and Rich de Blaquiere, Pharm D; Mark Johnston, R.Ph., executive director; Jenifer Marcus, DAG; Andy Snook, DAG; Fred Collings, Chief Investigator; Jan Atkinson, Senior Compliance Officer; Lisa Culley, Compliance Officer; Mike Brown, Compliance Officer; Gina Knittel, Compliance Officer; and Wendy Hatten.

The minutes from the October 27 & 28, 2010 meeting were reviewed. Dr. Chopski motioned to approve the minutes of October 27 & 28, 2010, with minor corrections. Mr. Fraser seconded. The motion carried unanimously.

Jim Tibbs, Idaho State Meth Coordinator for Strategic Applications International, presented a proposed change to the Retail Sales of Pseudoephedrine products, statute 37-3303. The current Idaho code is less restrictive then federal code, so the federal code takes precedence. Local law enforcement cannot enforce federal code, so they cannot utilize PSE log books for investigations and prosecute for misuse. Mr. Tibbs would like to run legislation that mimics the federal code so that local law officers have the ability to enforce violations. The Board supports the proposed legislation.

Taylor Neilson, R.Ph., Director of Pharmacy of West Valley Medical Center, presenting on behalf of the Idaho Society of Health-Systems Pharmacists (ISHP), proposed an amendment to the Board's pharmacist membership, detailed within Section 54-1707, Idaho Code. The proposed amendment would add the following verbiage: "The Board of Pharmacy shall have diverse pharmacy practice experience, with at least one (1) member having substantial experience in retail pharmacy and at least one (1) member having substantial experience in health system pharmacy, defined as hospital, health maintenance organization, long term care, or home care practice". Mr. Neilson then discussed changes that included replacing the term "health system" with "institutional" and providing an alternative definition. The Board was not provided a document that detailed said changes, as said changes were still in flux. . Mr. Neilson listed supporters of the proposed change, including ISHP, Idaho State University (ISU) School of Pharmacy students, the Idaho Hospital Association, the Capital Pharmacy Association and several individual members of these organizations. The Idaho State Pharmacy Association (ISPA) was reported to be neutral. The Board believes that all areas of Pharmacy are currently being represented adequately. The Board traditionally does not take a position on language that is not finalized. The Board is concerned that these proposed changes might restrict the Governor from appointing the most qualified

individual at any particular time. The Board remains neutral, in part because they are uncomfortable in taking a position on their own make up.

Mr. Johnston presented the agenda item entitled 2011 Legislation & Rule Review.

Prior to submitting the final version for publication, Mr. Johnston reviewed with Dr. Henggeler the many changes made to pending Rule 166, Immunization Record, pursuant to the Board's direction at the October 2010 Board meeting. Mr. Johnston reaffirmed said changes with the Board, and the Board approved of the changes.

Mr. Johnston discussed the following proposed changes regarding Sections 54-1729 and 54-1705, Idaho Code:

- The term "health care facility" has been replaced with "institutional facility", which is now defined.
- Telepharmacy within state lines and within a location that is not a pharmacy is allowed via the Rule 165, the 'independent practice of pharmacy', as discussed at the October 2010 Board meeting. The term 'pharmaceutical care' has been added, so that these locations may be registered as limited service outlets.
- The terms "Manufacturing" and "device" have been added to the definition of "drug outlet".
- A definition of "limited service" has been added.
- Added "doing business in or into Idaho" to "drug outlets shall annually register with the Board".
- Realized efficiency by listing "drug outlet" and "device" in 54-1729 (1), striking the terms several times from the draft of 54-1729 (2).
- "Facility operating a narcotic treatment program" has been struck from the draft of 54-1729(2), as this is now considered a limited service outlet.
- Included "licensure" in the title of 54-1729, and added "out-of-state mail service pharmacy" to the list.

The Board approved of the changes via unanimous consent.

Mr. Johnston suggested the Board consider removing the request for prescriptive authority on controlled substances, for fear of opposition, and replace with prescriptive authority for fluoride and immunizations. Dr. Chopski believes the Board should continue on with the original proposed language. Mr. Johnston then requested permission to modify as he suggests, if said fear is realized. The Board approved via unanimous consent.

Mr. Johnston concluded the agenda item entitled 2011 Legislation and rule review by asking if the Board has any other issues with the 2011 pending language, excepting the prospective drug review and counseling changes that are to be discussed later in the meeting. The Board had no additional issues.

The intent in providing hypothetical situations to the Board is for the Board to provide feedback to its prosecutor as to how to proceed on the factual allegations described

herein. No hearing has been conducted, and there is absolutely no guarantee as to the truthfulness of the allegations. Andy Snook, DAG, presented to the Board two hypothetical situations.

Hypothetical#1: A pharmacist accessed the Prescription Monitor Program (PMP) Controlled Substance Database (CSD) to look up data on co-workers, family members, and other people that he was not dispensing or considering dispensing to.

Issue #1: Would the Board consider delegating authority to the Board's staff to discipline via termination of the pharmacist on-line access to the PMP?

The Board agreed to delegate authority to the Board's staff, and to pursue additional discipline for egregious violations.

Issue #2: Should Idaho Code be changed in the future to allow a pharmacist access to the PMP when performing pharmaceutical care?

The Board is open to further discussion of possible statute change.

Hypothetical #2: A patient complained that a pharmacy dispensed a prescription without being offered counseling by a pharmacist. The prescription was for a new medication and the patient had specific questions about side effects related to a "black box" warning. The patient also complained that a confidential counseling area was not available.

The Board directed Board staff to file a complaint, schedule a hearing, and to not stipulate.

Mr. Johnston presented a proposal from the Idaho Pharmacy Leadership Counsel, comprised of members from ISHP, ISPA and ISU. Stepping forward for the presentation from the IPLC committee were Taylor Neilson, R.Ph., Samuel Hoagland R.Ph., and Dr. Paul Cady, as well as Pam Eaton of the Idaho Retailers Association (IRA). The proposed changes Section 54-1749, Idaho Code included:

- Strike Sections 54-1749, 54-1739, and 54-1750, Idaho Code.
- Move a severability clause to Section 54-1799, Idaho Code.
- Introduce new Section 54-1739, Idaho code that includes:
 - 1. Before dispensing any prescription, a pharmacist shall complete a prospective drug review, as otherwise defined in this chapter.
 - 2. Before dispensing a prescription for a new medication, or when otherwise deemed necessary or appropriate, a pharmacist shall counsel the patient or caregiver. Counseling shall cover those points as otherwise defined in this chapter, and shall include such supplemental written materials as required by law or customary in that practice setting. For refills or renewed prescriptions,

a pharmacist or a technician shall extend an offer to counsel the patient or caregiver. If such offer is accepted, a pharmacist shall provide such counseling as necessary or appropriate in the professional judgment of the pharmacist. All counseling or offers to counsel shall be 'face to face' when possible, but if not possible, than a 'reasonable effort' shall be made to contact the patient or caregiver by telephone. Nothing in this section shall require a pharmacist to provide counseling when a patient or caregiver refuses such counseling or when it is otherwise impossible. Patient counseling shall not be required for inpatients of a hospital or institutional facility when licensed health care professionals administer the drug(s).

 This section shall apply to all registered and licensed pharmacies, including mail service pharmacies. In cases of prescriber dispensing, the prescriber shall perform the prospective drug review and counseling as herein required of a pharmacist.

Much discussion ensued and the Board agreed to table their discussion regarding proposed language change to 54-1749 until after a lunch break.

Dr. Henggeler calls the meeting to order after a lunch break.

Mr. Neilson, R.Ph, noted that patients or caregivers within assisted living facilities where there is not a licensed health care professional administering the medications would be subject to the parameters of this proposal, his belief after hearing the debate that 'by telephone' should be struck, and that mail service pharmacy should not be exempt from counseling.

Dr. Paul Cady reiterated that the proposal was to create one standard of care for the citizens of Idaho.

JoAn Condie of ISPA commented that as a patient she would like to see counseling be treated the same whether walking into a pharmacy or receiving prescriptions from a mail service pharmacy.

Matthew Ray district manager for Sav-On gave comment in support the patient's right to refuse counseling and felt that professional judgment shouldn't be taken from the pharmacist. He also supported mandatory pharmacist counseling in an inpatient setting.

Judd Knudsen, R.Ph., commented that pharmacist counseling should not be mandatory on refilled prescriptions. Dr. Henggeler asked if Mr. Knudson would be comfortable with technicians offering to counsel on refills, and Mr. Knudsen was.

Ms. Eaton commented that IRA is supportive of IPLC's proposed changes, as written. They too want a level playing field with mail service pharmacy.

Board members resumed their discussion related to the proposed language change to Section 54-1749. The Board approved line numbers one (1) and three (3) as written. Line number two (2) was discussed sentence by sentence, and in great length by all the Board members, Mr. Johnston, Ms. Marcus, Mr. Hoagland, and Ms. Lynette Berggren, contracted paralegal.

Ms. Berggren expressed concern about HIPPA and other federal laws regulating the business use of a telephone.

Mr. Hoagland commented that he believed that Ms Berggren's concerns were invalid.

Dr Henggeler extended an offer of appreciation from the Board to the IPLC committee for their time and efforts.

Dr. Henggeler voiced several concerns, including impact of the words "by telephone". Dr. Henggeler was strongly opposed to an offer to counsel on refills, especially by technicians. Dr. Henggeler felt the language was complicated and hard to enforce.

Dr. Chopski motioned to accept the language as written, with removal of the words 'by telephone' from sentence number four (4). Mr. Fraser seconded. The motion carried unanimously.

In the reinstatement hearing regarding Carl Thulin, R.Ph., Dr. Henggeler presides. Ms. Marcus presented a summary of Mr. Thulin's case, including Mr. Thulin's voluntarily surrender of his license and controlled substance registration in lieu of the Board's 2010 complaint. Mr. Thulin presented his request for reinstatement, which included additional documentation concerning his license suspensions and/or revocation in lowa and Michigan, as well as his arrests and convictions for alcohol related crimes. Mr. Collings presented a statement on behalf of the Board staff, including a recommendation that Mr. Thulin's reinstatement be conditioned upon his contracting with Southworth Associates, the administrator of the Board's pharmacy recovery network (PRN), that he successfully complete a PRN approved 72 hour in-patient evaluation, and that he comply with any treatment plan recommended by the evaluator. The Board questioned Mr. Thulin, and Mr. Collings. Mr. Thulin and Mr. Collings both made closing comments. Dr. Chopski motioned to accept the Board Staff's recommendation. Dr. de Blaquiere seconded. The motion carried unanimously.

Mr. Snook notified the Board that the cases for Heel Inc. and Violeta Segura-Medina are still pending and were vacated from the agenda.

Mr. Snook presented Robert Johnston's stipulation and consent order involving violations of rule #184.04 for failing to strictly follow the instructions of the person making writing or ordering a prescription and Section 37-2722, Idaho Code, for dispensing a controlled substance without a written prescription. Mr. Johnston's

stipulated penalty included a one (1) year probation, \$2,000 in administrative fines, investigative costs, and a written plan of action. Dr. Chopski motioned to accept the stipulated order as written. Mr. Fraser seconded. The motion carried unanimously.

Mr. Johnston announced that the agenda items involving Lynette Berggren, contract paralegal, were again vacated due to a lack of time.

Mr. Johnston presented the travel calendar, and explained that Teresa Anderson was currently in Chicago to discuss issues concerning the Board's federal grant for the PMP's CSD. The National Association of Boards of Pharmacy has proposed a second hub through which Boards can share data.

Mr. Johnston and the Board members scheduled 2011 dates for the Board meetings for the year 2011, including March 3rd and 4th in Boise, April 28th in Pocatello, June 16th in Boise, August 4th and 5th in Boise and October 26th and 27th in Boise. Dr. Henggeler plans to attend the NABP Annual meeting May 21-24, 2011, in San Antonio, TX. Dr. de Blaquiere and Mr. Fraser plan to attend the NABP District meeting October 4-6, 2011, in Seattle, WA.

Glenn Luke presented the fiscal report to date;

- Expenses and revenue year to date are on budget.
- Controlled substance renewal count as of 8 a.m. on January 6, 2011;
 - o 7377 renewal post cards were mailed in October
 - 6,148 renewed online (70 late)
 - o 765 renewed with a paper renewal (1Late)
 - o 6.913 total renewed
 - 89% of the registrations renewed utilized the online renewal system.
 - 464 Have not renewed, about 6%
 - 5 days into the late registration mode we have found 1 registrant has been practicing without a registration.
- Current office space lease ends 2/28/2011. Due to several issues with building maintenance it was decided that a request for proposal (RPF) be sent out to commercial agents and owners to see what was available, and at what rate. The RFP begins January 7, 2011 and closes January 31, 2011. Depending on what comes back from the RFP, there is a possibility of a move. Cost associated with a move could be around \$10,000. Money saved by not having a Board meeting in Coeur d'Alene, ID in 2011, the sale of agency vehicles, and grant funds that have been acquired for travel that are normally paid by the agency will help fund the move.

Dr. Chopski requested status on 2012 budget request. At this point, a car purchase line item request was denied but all other request has been approved by the Governor. The budget request is awaiting review by the Legislature.

Mr. Fraser asked the Board for their opinion of pharmacy technicians taking blood pressure of patients in the area near the pharmacy without the pharmacist being

involved. The Board feels this would be ok, so long as the technician does a screening only and does not give additional patient care.

Dr. Chopski left the meeting at 4:37pm.

Mr. Johnston addressed the Board regarding a letter that Mr. Collings had sent out to 600 registered wholesalers, requesting practitioner RX item purchasing information. Findings on responses received and recorded to date include:

- Twenty five (25) wholesalers are distributing Rx items, including controlled substances, to Idaho practitioners
- Three (3) of those twenty five (25) ship veterinarian medications which leaves only 22 of concern
- Of the twenty five (25), one (1) company was selling prescription medications to an entity that is unauthorized to receive them
- Three (3) have no way to report the name of the person they are selling the
 prescription medication to. They can only identify the facility or building that
 they are shipping to. This is of concern because controlled substances are
 registered to the individual and not the facility. One of those individuals was
 asked and did recently voluntarily surrender his controlled substance
 registration
- Several investigations are underway

During inspector Q&A, Mike Brown expressed concern to the Board regarding three (3) compounding pharmacies that have been approached by a veterinarian in the magic valley area to make a compound medication that has been withdrawn from the market for human use. Dr. de Blaquiere commented that compounding must be done pursuant to a valid prescription. With a valid prescription it would be appropriate for the veterinarian to use the product in his office but would be considered manufacturing if the veterinarian dispensed the product. Mr. Johnston stated that he recently held the first compounding committee meeting, and this issue was discussed.

Mr. Fraser motioned to adjourn, Dr. de Blaquire seconded. The vote was unanimous. Meeting adjourned at 4:51 p.m.